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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER
CHICAGO, IL 60606-6357

EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/905,732	CHADWICK ET AL.	
Examiner	**Art Unit**	
Amy M. DeCloux	1644	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19* is/are allowed.

6)☒ Claim(s) *20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Notice to comooply with requirements for Sequence Disclosures.

DETAILED ACTION

Claims 19-31 are pending and are under consideration.

Election/Restrictions

Applicant's note in the Remarks section of the paper filed 11-1-02 (Paper No. 10) that the claims subjected to the restriction requirement mailed 10-02-02 (Paper No. 7), are no longer pending, in accordance with a preliminary amendment filed 7-13-01 (Paper No. 1.5), is acknowledged. Accordingly, claims 1-18 have been cancelled and said restriction requirement has been withdrawn.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Specifically a reference to Application Number 09/240,639, now US Patent 6350447, is required.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Sequences, which lack SEQ ID NO: tags, are disclosed throughout the specification including in page 95, lines 28-29, page 98, line 26, page 100, lines 27, 28, 30 and 33, page 101, lines 1, 18, 19 and 25, and page 103, lines 7-8. Applicants are required to resubmit a substitute disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01. Specifically, hyperlinks are disclosed on page 99, lines 19 and 28-29, and on page 100, lines 19-20 and 22. Applicant is requested to carefully review the submitted specification for any and all embedded hyperlinks and/or other form of browser-executable code.

The abstract of the disclosure is objected to because the word "novel" is stated in line 1 of the Abstract. Patents are presumed to be novel. Correction is required. See MPEP § 608.01(b).

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, Claim 25 encompasses a broader breadth of polynucleotides compared to that of Claim 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 24-28 and 30 are indefinite in their recitation of the phrase "hybridizes under highly stringent conditions" in line 2 of claim 24, because the stringent conditions are disclosed in exemplary terms only on page 11 of the instant specification. Incorporating a specific set of hybridization conditions into the instant claims would overcome this rejection.

B) Claims 23, 25-28 and 30 are indefinite in their recitation of the phrase "at least about 90% sequence identity" recited in claim 23, because the minimum sequence identity is not clear.

C) Claims 20, 29 and 31 are indefinite in their recitation of the phrase "encoding the amino acid sequence of SEQ ID NO:6" because it is not clear whether open or closed language is intended.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A) Claims 21-22, 24-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

i) Claim 21 and dependent claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a fragment of the amino acid sequence of SEQ ID NO:6, said fragment having phosphohydrolase activity as recited in claim 21. Claim 22 and dependent claims are drawn to the polynucleotide of claim 21 wherein said nucleotide sequence is a fragment of SEQ ID NO:5. The instant claims also encompass a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell.

ii) Claims 24 and 26, and dependent claims are drawn to an isolated polynucleotide encoding a polypeptide having phosphohydrolase activity, wherein said polynucleotide hybridizes under highly stringent conditions to the complement of SEQ ID NO:5 or its complement.

iii) Claim 25 and dependent claims is drawn to the polynucleotide of any one of claims 20, 21, 23 or 24, that comprises nucleotides 247-1530, 385-450, 613-660, 745-807 or 823-888 of SEQ ID NO:5.

i) The instant specification describes an isolated polynucleotide comprising a nucleotide sequence (SEQ ID NO:5), encoding the amino acid sequence of SEQ ID NO:6, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell. However, the instant disclosure of a nucleotide sequence, (SEQ ID NO:5), encoding the amino acid sequence of SEQ ID NO:6, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell, does not adequately describe the scope of the claimed fragments of said sequences, each of which encompasses a substantial variety of subgenera, for two reasons.

First, Page 18 of the specification defines the term "fragment" as a stretch of amino acids of at least 5 amino acids long, and page 11 of the specification defines the term "polynucleotide fragment" as being at least about 15 nucleotides in length. However, the specification does not describe a single fragment of SEQ ID NO:5 or SEQ ID NO:6, wherein said fragment has phosphohydrolase activity or encodes an amino acid fragment that has phosphohydrolase activity.

Second, since the polynucleotide of Claims 21-22, 25-28 and 30 comprises a nucleotide sequence encoding a fragment of the amino acid sequence of SEQ ID NO:6, or a nucleotide

sequence that comprises a fragment of SEQ ID NO:5, said fragments can also encompass an indeterminate number and type of additional nucleic acids, in addition to the length of 15 nucleotides in length. There is no description of the required structural and specific phosphohydrolase functional features encoded by the wide range of fragments encompassed by the instant claims, or of the conserved regions that would be critical for these features. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the fragments encompassed. Therefore, the structure of an isolated polynucleotide comprising a nucleotide sequence encoding a fragment of the amino acid sequence of SEQ ID NO:6, said fragment having phosphohydrolase activity, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of the polynucleotide encompassed by the instant claims, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell, without further description from the instant specification.

It is noted that though the claimed invention is directed to polypeptides and not cDNA, the principle of the following still holds for said polypeptides: a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

ii) Nor does the instant disclosure of polynucleotide sequence (SEQ ID NO:5) encoding the amino acid sequence of SEQ ID NO:6 adequately describe the scope of the claimed isolated polynucleotide encoding polypeptides having phosphohydrolase activity comprising an amino acid sequence encoded by a polynucleotide that hybridizes under highly stringent conditions to the complement of nucleotide sequence of SEQ ID NO:5. However, by reciting hybridization language, said polypeptide can be of an indeterminate length (smaller or larger than SEQ ID NO:6) and also encompass an indeterminate number and combination of amino acid substitutions in SEQ ID NO:6. Since the applicants have not disclosed a single polynucleotide encoding a polypeptide having phosphohydrolase activity that hybridizes under highly stringent conditions to the complement of nucleotide sequence of SEQ ID NO:5, other than SEQ ID NO:5 itself, the invention encompassing said claimed polynucleotide having phosphohydrolase activity comprising an amino acid sequence encoded by a polynucleotide that hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:5 or its complement, is not adequately described along the lines of reasoning discussed in the previous paragraphs.

iii) Nor does the instant disclosure of a polynucleotide sequence (SEQ ID NO:5) adequately describe the scope of the claimed polynucleotide that comprises nucleotides 385-450, 613-660, 745-807 or 823-888 of SEQ ID NO:5, as recited in claim 25. It is noted that claim 25 does not include functional language when dependent on claim 20. Therefore, said polynucleotide can be of an indeterminate length and also encompass an indeterminate number

and combination of additional polynucleotides, and polynucleotide segments 385-450, 613-660, 745-807 or 823-888 of SEQ ID NO:5 can be in any order. Since the applicants have not disclosed a single polynucleotide that comprises nucleotides 247-1530, 385-450, 613-660, 745-807 or 823-888 of SEQ ID NO:5, except nucleotides 247-1530, which encodes amino acid SEQ ID NO:6, the invention encompassing said claimed polypeptides, is not adequately described along the lines of reasoning discussed in the previous paragraphs.

B) Claims 21-22, 24-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 and dependent claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a fragment of the amino acid sequence of SEQ ID NO:6, said fragment having phosphohydrolase activity as recited in claim 21. Claim 22 and dependent claims are drawn to the polynucleotide of claim 21 wherein said nucleotide sequence is a fragment of SEQ ID NO:5. The instant claims also encompass a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell.

The instant specification discloses an isolated polynucleotide comprising a nucleotide sequence (SEQ ID NO:5), encoding the amino acid sequence of SEQ ID NO:6, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell . However, the instant specification does not provide adequate guidance and direction regarding how to make and use an isolated polynucleotide comprising a nucleotide sequence encoding any fragment of the amino acid sequence of SEQ ID NO:6, said fragment having phosphohydrolase activity, nor does the instant specification provide adequate guidance and direction regarding how to make and use a polynucleotide of claim 21 wherein said nucleotide sequence is any fragment of SEQ ID NO:5, which encompasses a substantial number of fragments, for two reasons.

First, Page 18 of the specification defines the term "fragment" as a stretch of amino acids of at least 5 amino acids long, and page 11 of the specification defines the term "polynucleotide fragment" as being at least about 15 nucleotides in length. However, the specification does not disclose a single fragment of SEQ ID NO:5 or SEQ ID NO:6, wherein said fragment has phosphohydrolase activity or encodes a amino acid fragment that has phosphohydrolase activity. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the fragments of the nucleotides encompassed by the instant claims.

Second since the polynucleotide of the instant claims comprises a nucleotide sequence encoding a fragment of the amino acid sequence of SEQ ID NO:6, or said nucleotide sequence is

a fragment of SEQ ID NO:5, said fragments can also encompass an indeterminate number and type of additional nucleic acids, in addition to the length of 15 nucleotides in length.

Since the nucleic acid sequence of a polynucleotide determines its protein coding properties, predictability of which changes can be tolerated in a polynucleotide's nucleic acid sequence and still retain similar functions and properties requires a knowledge of, and guidance with regard to which nucleic acids in the nucleotide sequence, if any are tolerant of modification and which are conserved (ie., expectedly intolerant to modification), and detailed knowledge of the ways in which the product's structure relates to its functional usefulness. However, the problem of predicting functional aspects of the product in terms of what changes can be tolerated is complex and well outside the realm of routine experimentation. This complexity is due in part to the fact that the relationship between the amino acid sequence of a peptide (and its corresponding encoding nucleic acid sequence) and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al., (V), newly cited, in The Protein Folding Problem and Tertiary Structure Prediction,1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495). Therefore, there is no evidence of record to show that one skilled in the art would be able to practice the invention as claimed without an undue amount of experimentation.

Therefore, with the exception of a nucleotide sequence (SEQ ID NO:5), encoding the amino acid sequence of SEQ ID NO:6, the instant specification provides insufficient guidance and direction regarding the required structural and specific phosphohydrolase functional features of the wide range of fragments encompassed by the instant claims, or of the conserved regions that would be critical for the recited phosphohydrolase features. Therefore, it would require undue experimentation by one of skill in the art to predict A) the sequence of said fragments or B) the sequence of the additional amino acid residues that are to be included in the recited nucleotides, a vector comprising said polynucleotide, a host cell comprising said vector, and a method of making a CD39L4 polypeptide comprising said host cell without further guidance and direction from the instant specification.

ii) By reciting hybridization language in claim 24, the recited polynucleotide encoding a polypeptide having phosphohydrolase activity, wherein said polynucleotide hybridizes under highly stringent conditions to the complement of SEQ ID NO:5, can be of an indeterminate length (smaller or larger than SEQ ID NO:5) and also encompass an indeterminate number and combination of nucleotide substitutions in SEQ ID NO:5. Since the applicants have not disclosed a single polynucleotide encoding a polypeptide having phosphohydrolase activity comprising a polynucleotide that hybridizes under highly stringent conditions to the complement of SEQ ID NO:5, other than SEQ ID NO:5, or the nucleotides encoding the mature portion thereof, and the prior art does not teach any said molecule, and since further the prior art and the instant disclosure do not provide compensatory structural or correlative teachings to enable one of skill to predict which of the polypeptides encompassed by the instant claims will have phospohydrolase activity, it would require undue experimentation for one of skill to predict which polynucleotide hybridizes under highly stringent conditions to the complement of SEQ

ID NO:5, and still retains the ability to encode a polypeptide having phosphohydrolase activity (other than SEQ ID NO:5 itself), without further guidance from the specification.

iii) Other than SEQ ID NO:5, the mature portion encoding region thereof, and nucleotides 247-1530, the specification does not disclose the claimed polynucleotide that comprises nucleotides 385-450, 613-660, 745-807 or 823-888 of SEQ ID NO:5, as recited in claim 25. It is noted that claim 25 does not include functional language when depending on claim 20, and therefore, function is not a limiting factor in the breadth of the claims. Therefore, the function of the encoded products is not a limiting factor, and thus the claimed nucleotide can be of an indeterminate length (smaller or larger that SEQ ID NO:5) and also encompass an indeterminate number and combination of additional nucleotides and nucleotide substitutions in SEQ ID NO:5, and further, nucleotides 385-450, 613-660, 745-807 or 823-888 can be in any position of the polynucleotide sequence and be in any order. Therefore it would require undue experimentation to make and use the breadth of said polynucleotides, except for that of SEQ ID NO:5, the mature portion encoding region thereof, and nucleotides 247-1530, without further guidance and direction from the specification.

Allowable Subject Matter

Claim 19 contains allowable subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
January 11, 2003

Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640